PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	**Ravenscroft**
Application No.:	**08/873484**
Filed:	**June 12, 1997**
For:	**Stent Delivery System**
Examiner:	**Kevin T. Truong**
Group Art Unit:	**3734**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2-6925-US02

APPEAL BRIEF

This is an Appeal Brief for the above-identified file. A Notice of Appeal was filed in this case on June 4, 2008.

The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

(B) Table of Contents

(C) Real Party in Interest

The Application is assigned to Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(D) Related Appeals and Interferences

At present there are no related appeals or interferences.

(E) Status of Claims

In the final Office Action of January 8, 2008, claims 1-9, 11-17, 20 and 22 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 5,474,563 to Myler et al. and are the subject of this appeal.

Claims 10, 18-19, 21 and 23 have been cancelled.

(F) Status of Amendments

Subsequent to the Final Office Action of January 8, 2008, Applicant filed an Amendment After Final and request for reconsideration on March 6, 2008. In the Advisory Action of April 15, 2008, the Examiner indicated that the proposed amendment to claim 20 in the Amendment After Final of March 6, 2008 would not be entered because it raises new issue that would require further consideration.[1] However, Applicant notes that the proposed amendment was made to clarify that, as is recited in independent claims 1 and 12, the ring of the sheath is assisting in the compression of the stent. Applicant submits that entry of this amendment would not have raised new issues and would have placed the application in better form for appeal.

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[1] Amendment proposed in the Amendment After Final filed March 6, 2008:

A method for delivering and selectively deploying a stent comprising the steps of:

A) inserting an axially extending catheter within the body of a patient, the catheter having an exterior sheath, the exterior sheath having a ring, the ring forming a distal end of the exterior sheath, with a stent in a compact form proximate a distal end of the catheter, the stent underlying the sheath and overlying at least two rings, the ~~at least two rings~~ ring of the exterior sheath assisting in the compression of the stent to the compact form from a partially deployed form,

B) urging the distal end of the catheter through the patients body to position the distal end at a selected location, and

C) selectively displacing the at least two rings relative to the sheath to urge the displacement of said stent relative to the sheath to enable selective extension and retraction of the stent relative to a distal end of the sheath.

(G) Summary of Claimed Subject Matter

A summary of representative claims and a non-limiting listing of locations where support may be found [bracketed citations] is provided as follows:

Independent claim 1 recites a stent delivery system for transporting and deploying an expansible stent [pg. 11, lines 13-15]. The stent delivery system comprises a delivery means for positioning the stent at a selected position in the patient's body and a deployment means for selectively deploying and retracting the stent relative to said sheath [pg. 9, lines 7-17; pg. 14, lines 3-14]. The delivery means includes a sheath and an inner core [pg. 11, lines 7-10 and 19-23]. The sheath normally overlies the stent in its compact transport form [pg. 9, lines 10-12; pg. 11, lines 19-22]. The stent has an inner surface [pg. 11, lines 13-17]. The sheath has a ring forming a distal end of the sheath [pg. 17 lines 12-16]. The ring assists in the compression of the stent to the compact transport form from a partially deployed form [pg. 17, lines 12-16]. The inner core normally underlies the stent in its compact transport form [pg. 9, lines 10-12; pg. 11, lines 13-15]. The deployment means includes at least two rings attached to and extending from said inner core and engaging the inner surface of the stent in its compact condition [pg. 9, lines 13-17].

Dependent claim 4 recites a stent delivery system as recited in 3 wherein said delivery means further includes a handle disposed at a proximal end of said sheath and said inner core [pg. 11, lines 5-10 and 19-24]. The handle has a first actuator means for proximally retracting said sheath relative to said inner core and a second actuator means for distally displacing said inner core relative to said sheath [pg. 11, lines 19-24; pg. 14, lines 19-23; and pg. 16, line 20 to pg. 17, line 1]. Selective manipulation of said first and second actuator means enables selective deployment of the stent in an expanded form outside of said sheath and retraction of the stent within said sheath from a partially deployed state [pg. 11, line 24 to pg. 12, line 3].

Dependent claim 5 recites a stent delivery system as recited in claim 1 wherein

said delivery means is adapted for use in a working channel of an endoscopic device of the type having a viewing channel [pg. 17, lines 23-25; pg. 16, lines 2-6; pg. 18, lines 11-23]. Said delivery means includes visible indicia proximate its distal end visible through the viewing channel of the endoscopic device indicating the extent of deployment of the stent [pg. 16, lines 2-6; pg. 18, lines 11-23].

Dependent claim 6 recites a stent delivery system as recited in claim 5 wherein said delivery means further includes a handle disposed at a proximal end of said sheath and said inner core [pg. 11, lines 5-10 and 19-24]. The handle has a first actuator means for proximally retracting said sheath relative to said inner core and a second actuator means for distally displacing said inner core relative to said sheath [pg. 11, lines 19-24; pg. 14, lines 19-23; and pg. 16, line 20 to pg. 17, line 1]. Manipulation of said first and second actuator means enables selective deployment of the stent in an expanded form outside of said sheath and retraction of the stent in the compact form within said sheath [pg. 11, line 24 to pg. 12, line 3].

Dependent claim 7 recites a stent delivery system as recited in claim 1 where the at least two rings comprise a first ring and a second ring, the second ring axially spaced from said first ring [pg. 11, lines 18-19]. Said first and second rings engage the stent proximate a proximal end of the stent in its compact form [Fig. 1, reference numerals 23 (ring) and 20 (stent)].

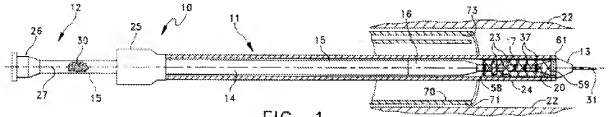


FIG. 1

Dependent claim 8 recites a stent delivery system as recited in claim 7 wherein said delivery means further includes a handle disposed at a proximal end of said sheath and said inner core [pg. 11, lines 5-10 and 19-24]. The handle has a first actuator means for proximally retracting said sheath relative to said inner core and a second actuator means for distally

displacing said inner core relative to said sheath [pg. 11, lines 19-24; pg. 14, lines 19-23; and pg. 16, line 20 to pg. 17, line 1]. Manipulation of said first and second actuator means enables selective deployment of the stent in an expanded form outside of said sheath and retraction of the stent within said sheath from a partially deployed condition in the compact form [pg. 11, line 24 to pg. 12, line 3].

Dependent claim 9 recites a stent delivery system as recited in claim 8 wherein said delivery means is adapted for use in a working channel of an endoscopic device of the type having a viewing channel [pg. 17, lines 23-25; pg. 16, lines 2-6; pg. 18, lines 11-23]. The delivery means includes visible indicia proximate its distal end visible through the viewing channel of the endoscopic device indicating the extent of deployment of the stent [pg. 16, lines 2-6; pg. 18, lines 11-23].

Dependent claim 11 recites a stent delivery system as recited in claim 1 wherein said delivery means is adapted for use in a working channel of an endoscopic device of the type having a viewing channel [pg. 17, lines 23-25; pg. 16, lines 2-6; pg. 18, lines 11-23]. The delivery means includes visible indicia proximate its distal end visible through the viewing channel of the endoscopic device indicating the extent of deployment of the stent [pg. 16, lines 2-6; pg. 18, lines 11-23].

Independent claim 12 recites an elongated, tubular stent delivery system for transporting a stent in a compact form within a patient's body for selective deployment of the stent in an expanded form within a patient's vessel [pg. 9, lines 7-17; pg. 14, lines 3-14]. The stent delivery system comprises a distal end region and a proximal end region [pg. 11, lines 5-7]. The distal end region includes a sheath and a flexible core at the distal end region for overlying and underlying, respectively a stent carried at the distal end region of the delivery system in the compact form [pg. 9, lines 10-12; pg. 11, lines 7-10, 13-15 and 19-23]. The stent has an inner surface [pg. 11, lines 13-15]. The proximal end region includes a first handle portion connected to the sheath and a second handle portion connected to the core to enable relative axial

displacement of the sheath and the core [pg. 11, lines 9-24]. The improvement comprises at least two rings engaged to and extending from the core to engage the inner surface of the stent disposed in the compact form within said sheath such that upon the displacement of the sheath relative to the core the stent moves relative to the sheath [pg. 11, line 18; pg. 12, line 3; and pg 14, lines 3-23]. The sheath comprises a ring forming a distal end of the sheath [pg. 17, lines 12-16]. The ring assists in the compression of the stent to the compact form from a partially deployed form [pg. 17, lines 12-16].

Dependent claim 15 recites a tubular stent delivery system as recited in claim 14 wherein said stent has portions with an inner diameter ID_{max} disposed between portions of the stent having its minimum inner diameter where $ID_{min} < D_r < ID_{max}$ and each of said at least two rings is disposed intermediate the minimum inner diameter portions [pg. 13, line 9 to pg. 14, line 18 and Fig. 3, reference numerals 20 (stent), 20b (overlapping portions of stent), 20c (single wire portions of stent), 23 (ring)].

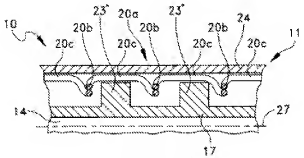


FIG. 3

Dependent claim 16 recites a tubular stent delivery system as recited in claim 15 wherein said delivery system is adapted for use in a working channel of an endoscopic device of the type having a viewing channel [pg. 17, lines 23-25; pg. 16, lines 2-6; pg. 18, lines 11-23]. The distal end of the stent has indicia proximate the distal end of the core. The indicia are of the type visible through the viewing channel of an endoscopic device and indicate the extent of deployment of the stent [pg. 16, lines 2-6; pg. 18, lines 11-23].

Independent claim 20 recites a method for delivering and selectively deploying a stent comprising the steps of inserting an axially extending catheter within the body of a patient, urging the distal end of the catheter through the patient's body to position the distal end at a selected location, and selectively displacing the at least two rings relative to the sheath to urge the displacement of said stent relative to the sheath to enable selective extension and retraction of the stent relative to a distal end of the sheath [pg. 9, line 22 to pg. 10, line 2; pg. 11, line 18; pg. 12, line 3; pg 14, lines 3-23]. The catheter has an exterior sheath that has a ring forming a distal end of the exterior sheath [pg. 17, lines 12-16]. A stent in a compact form is proximate a distal end of the catheter [pg. 11, lines 13-15]. The stent underlies the sheath and overlies at least two rings [pg. 9, lines 10-12; pg. 14, lines 3-6]. The at least two rings assist in the compression of the stent to the compact form from a partially deployed form [pg. 9, lines 13-17; pg. 9, line 22 to pg. 10, line 2; pg. 17, lines 12-16].

Dependent claim 22 recites a method for delivering and selectively deploying a stent as recited in claim 20 wherein the stent is self-expansive and said step of selectively displacing the at least two rings relative to the sheath to urge displacement of said stent relative to the sheath to enable selective extension and retraction of the stent relative to a distal end of the sheath includes engaging the inner surface of the stent between portions of the stent having a minimum inner diameter [pg. 13, line 9 to pg. 14, line 18 and Fig. 3, reference numerals 20 (stent), 20b (overlapping portions of stent), 20c (single wire portions of stent), 23 (ring)].

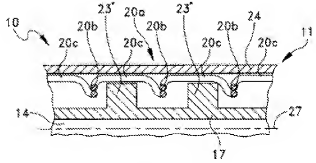


FIG. 3

(H) Grounds of Rejection to be Reviewed on Appeal

1. Whether the Examiner erred in rejecting claims 1-9, 11-17, 20 and 22 under 35 U.S.C. §102(e) as being anticipated by U.S. 5,474,563 to Myler et al.

(I) Argument

1. The Examiner erred in rejecting claims 1-9, 11-17, 20 and 22 under 35 U.S.C. §102(e) as being anticipated by U.S. 5,474,563 to Myler et al.

In the Final Office Action, claims 1-9, 11-17, 20 and 22 were rejected under 35 USC §102(e) as being anticipated by Myler.

Independent claims 1 and 12 and claims dependent therefrom

Independent claims 1 and 12 recite in part, "the ring forming a distal end of the sheath, the ring assisting in the compression of the stent to the compact transport form from a partially deployed form." As recited in independent claims 1 and 12, a sheath overlies the stent when it is in the compact transport form. Applicant submits that Myler does not teach each and every element of independent claims 1 and 12 (MPEP §2131 "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference").

As a reference for the discussions of Myler, Applicant has provided Figs. 4, 9 and 11 of Myler with Figs. 4 and 11 being annotated. Fig. 4 of Myler shows the two expandable extraction halos 62,66 in an expanded position:

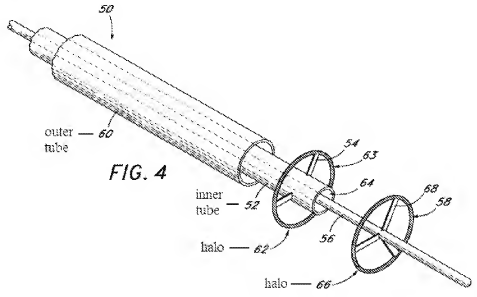
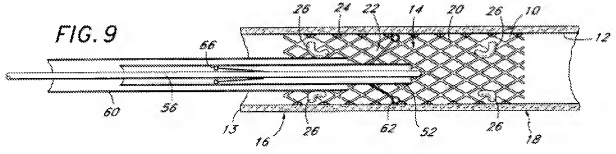
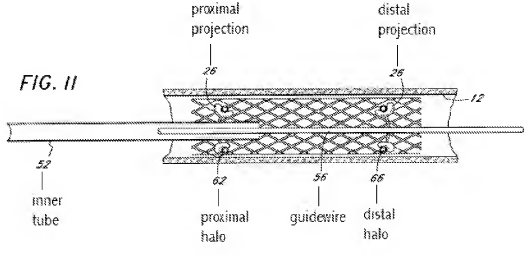


FIG. 4

Fig. 9 of Myler shows the relationship of the outer tube 60 to the projections 26 of the stent 10:



In Fig. 11 of Myler the proximal and distal engagement structures are engaged and the stent is radially reduced:



a. Myler Does Not Teach That The Sheath Has A Ring That Assists In The Compression Of The Stent To The Compact Transport Form From A Partially Deployed Form

The Examiner asserted that "applicant's ring is just the distal tip of the sheath" and that "[s]imilarly, Myler's end of the sheath also constitutes a ring, as it is an annular surface" (Final Office Action dated January 8, 2008 at pg. 3).

Applicant submits that Myler does not teach that the outer tube 60 has a ring that assists in the compression of the stent to the compact transport form from a partially deployed form (see Amendment submitted Oct. 25, 2007 at pp. 8-9).

In describing a procedure for extracting a stent, Myler states that the two halos 62,66, one seated in the proximal projection 26 and one seated in the distal projection 26, are advanced in opposite directions by the inner tube 52 and guide wire 56, respectively (Myler, col. 10, lines 54 to 59). Because the projections 26 are engaged to or integral with the stent 10, this movement of the proximal and distal projections 26 axially elongates the tubular stent 10 and reduces the cross-sectional area of the stent 10 so that it can be removed from the body (Myler, col. 6, line 63 to col. 7, line 6; col. 10, lines 54 to 66). In one embodiment, the stretched stent can subsequently be advanced into the distal end of the outer tube 60 (Myler, col. 10, line 66 to col. 11, line 3). Thus, it is the halos 62,66 which assist in the compression of the stent 10 in this method of Myler, not the outer tube 60. The halos 62,66 do not form a part of the outer tube 60. Therefore, the outer tube 60 of Myler does not assist in the compression of the stent 10.

Another method described in Myler is for removing an implanted stent that is tapered at its proximal end (Myler, col. 11, lines 20-51, Fig. 3). However, the removal catheter used in this method does not comprise "a deployment means comprising at least two rings attached to and extending from the inner core and engaging the inner surface of the stent in its compact condition," contrary to independent claims 1 and 12.

Therefore Myler does not teach each and every element of the instant claims.

b. The Examiner's Proposed Methods of Using the Device of Myler Do Not Anticipate the Instant Claims

In response to Applicant's assertion that Myler does not teach or suggest each and every element of the instant claims, the Examiner proposed alternative methods of using the device of Myler, which were not described in Myler, and asserted that these proposed methods anticipated the instant claims:

> the distal end of the outer sheath would be capable of assisting in stent compression, if one so desired, by merely retracting the inner members relative to the sheath 60, or moving the sheath distally over the inner members. ***As the distal end (ring) of***

> ***the sheath contacted the stent or the halos, it would cause compression of the stent and allow the stent to be withdrawn into the distal end of the outer sheath 60***.
> (emphasis added)

Thus, the methods proposed by the Examiner are:

a) merely retracting the inner members relative to the sheath 60; and

b) moving the sheath distally over the inner members.

These methods do not teach each and every element of the instant claims. Myler does not teach or suggest the methods of use proposed by the Examiner.[2]

Applicant submits that the result of either method proposed by the Examiner would be the same. If the sheath 60 is moved distally over the inner members, e.g. halos 62,66 and spokes 63,68, or if the inner member are moved proximally toward the sheath 60, the sheath 60 would contact the proximal spokes 63 or vice-versa. Continued pressure of the sheath 60 against the proximal spokes 63 would result in either i) the proximal halo 62 popping out of, or becoming unseated from, the proximal projections 26, or ii) the proximal halo 62 remaining seated in the proximal projections 26. These two alternative scenarios are discussed below in sections (i) and (ii).

i. The Proximal Halo/Spokes Pop Out of the Proximal Projections – the Stent Remains Within the Vessel – Sheath is Not Assisting in the Compression of the Stent to the Compact Transport Form From a Partially Deployed Form

One scenario of the methods proposed by the Examiner is that the proximal halo/spokes 62,63, which have been seated in the proximal projections 26, would pop out of, or become unseated from, the proximal projections 26 due to the force of the sheath 60 against the proximal halo/spokes 62,63.

Myler teaches that ***self-expandable stents*** are used when the removal catheter, shown in Figs. 9 and 11 above, is used as an insertion catheter (Myler, col. 11, lines 52-54). Thus, even if the stent 10 had decreased in diameter due to the pressure of the sheath 60 against

[2] There is no indication that Examiner's proposed methods of using the device of Myler would actually work in the manner suggested by the Examiner. To the contrary, Applicant submits that the Examiner's proposed methods would not work in the manner suggested by the Examiner.

the proximal halo/spokes 62,63, when the proximal halo/spokes 62,63 pop out of the proximal projections 26, the self-expandable stent 10 would revert back into its implanted diameter which would prevent the stent from being retracted into the sheath 60 (see Myler, col. 11, line 63 to col. 12, line 2 "Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall. Thereafter, the annular halos 62,66 … are withdrawn within the tubular body, so that they may be proximally withdrawn from within the implanted stent."). Therefore, the sheath does not assist in the compression of the stent to the compact transport form.

For at least this reason, this scenario of the Examiner's proposed methods of using the device of Myler does not anticipate the instant claims because the proposed methods do not teach each and every element of the instant claims.

ii. Proximal Halo Remains in the Proximal Projections – Sheath is Withdrawn – Stent Reverts to Expanded Diameter and Remains Within the Vessel – Sheath is Not Assisting in the Compression of the Stent to the Compact Transport Form

A second scenario of the methods proposed by the Examiner is that the proximal halo/spokes 62,63, which have been seated in the proximal projections 26, would remain seated in the proximal projections 26 despite the force of the sheath 60 against the proximal halo/spokes 62,63.

Applicant submits that since the proximal halo/spokes 62,63 remain seated in the proximal projections, the sheath 60 will push against the proximal spokes 63, which are seated in the proximal projections 26. Although Myler does not state what materials can be used to make the sheath 60, if the sheath 60 is formed from a material with the necessary strength/stiffness, the sheath 60 could push the proximal spokes 63 in the proximal direction. The movement of the proximal spokes 63 could cause the stent 10 to move in response to the tension of the proximal spokes 63 on the proximal projections 26 which are engaged to or integral with the stent 10. Thus, it is possible that the tension of the sheath 60 against the proximal halo/spokes 62,63 could push the proximal halo/spokes 62,63 closer towards the outer surface of the sheath 60 which could bring the stent 10 closer to the outer surface of the sheath 60. However, as mentioned

above, if the sheath 60 material is not strong/stiff enough, then the tension of the sheath 60 against the proximal halo/spokes 62,63 would not push the proximal halo/spokes 62,63 closer towards the outer surface of the sheath 60.

Even if the sheath 60 did cause the proximal halo/spokes 62,63 to bring the stent 10 closer to the outer surface of the sheath 60, only a portion of the proximal end of the stent 10 would be compressed. This is due to the fact that the distal movement of the sheath 60, and therefore the length of the stent portion that can be compressed, is limited in part by the length of proximal spokes 63, which are seated in the proximal projections 26. Since the length of the halo 62 is less than the length of the stent 10, if the sheath 60 does push the proximal halo/spokes 62,63 towards the outer surface of the sheath 60, only a portion of the proximal end of the stent 10 could be compressed in this scenario.[3]

Furthermore, the portion of the stent 10 would be compressed inwards towards the outer surface of the sheath 60 since the sheath 60 would be within the stent 10 when it is in contact with the proximal halo/spokes 62,63. As discussed above, in the instant claims the sheath is overlying the stent when the stent is in its compact transport form. Therefore, in order for the stent to be in the compact transport form as recited in the instant claims, the sheath 60 would need to be withdrawn proximally out of the lumen of the stent 10 so that the proximal end of the stent 10 can be withdrawn into the distal end of the sheath 60.

However, if the tension of the sheath 60 against the proximal halo/spokes 62,63 did reduce the diameter of the self-expanding stent 10, without the tension of the sheath 60 against the proximal halo/spokes 62,63 the stent 10 would revert to its expanded diameter after the sheath 60 is withdrawn, which would prevent the stent 10 from being retracted into the sheath 60 (see Myler, col. 11, line 63 to col. 12, line 2).

Therefore, in this scenario, the sheath 60 does not assist in the compression of the stent 10 to the compact transport form. For at least this reason, this scenario of the Examiner's proposed methods of using the device of Myler does not anticipate the instant claims because it does not teach each and every element of the instant claims.

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[3] Myler states that the halo 62 can extend from about 0.010 inches to about 0.050 inches or greater beyond the outer radius of the tubular body 52 and that the axial length of the stent 10 will typically range from 1 cm (0.4 inches) to about 3-5 cm (1.2 to 2 inches) (Myler, col. 6, lines 30-36; col. 8, lines 41-43).

Conclusion

The specification of Myler does not teach each and every element of the instant claims. The Examiner's proposed methods of using the device of Myler are not supported by Myler. The Examiner's proposed methods do not teach each and every element of the instant claims.

For at least these reasons, Myler does not anticipate the instant claims. Applicant requests reversal of the rejection.

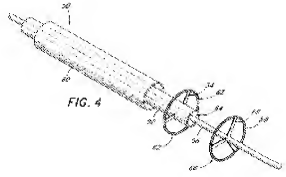
Dependent claims 4, 6, and 8 and Dependent claims 5, 9, 11, and 16

Dependent claims 4, 6 and 8 each recite in part "wherein said delivery means further includes a handle … having a first actuator means for proximally retracting said sheath relative to said inner core and a second actuator means for distally displacing said inner core relative to said sheath."

Dependent claims 5, 9, 11 and 16 each recite in part, "wherein said delivery means is adapted for use in a working channel of an endoscopic device of the type having a viewing channel, said delivery means including visible indicia proximate its distal end visible through the viewing channel of the endoscopic device indicating the extent of deployment of the stent."

As discussed above, Myler does not teach each and every element of independent claims 1 and 12, from which these claims depend. Furthermore, Applicant submits that Myler does not teach each and every element of claims 4, 6 and 8 which depend upon claim 1, and that Myler does not teach each and every element of claims 5, 9, 11, and 16, which depend upon claim 12.

Applicant notes that Myler provides partial views of a catheter in Figs. 4-8 and 15, however, these partial views do not show the proximal end of the catheter and do not show an endoscopic device with a working channel and a viewing channel:



Thus, the figures of Myler do not teach a handle or and endoscopic device with a working channel and a viewing channel.

Myler discusses catheters in the detailed description (see col. 7, lines 52, 54, 58, 63 and 66; an extraction catheter at col. 8, lines 1 to col. 9, line 65; col. 10, line 1; a method of extracting a stent with an extraction catheter at col. 10, line 31 to col. 11, line 3; col. 11, lines 22-23; using the extraction catheter to deliver a stent at col. 11, line 53 to col. 12 line 10; col. 14 line 36; col. 15, line 66; an insertion/retrieval catheter at col. 16, line 33 to col. 18, line 20; a method for retrieving a stent with the retrieval catheter at col. 18, line 21-50; and implanting a stent with the retrieval catheter at col. 18, line 51 to col. 19, line 9). Applicant submits that these passages do not teach all the elements of dependent claims 4, 6 and 8 and do not teach all the elements of dependent claims 5, 9, 11, and 16.

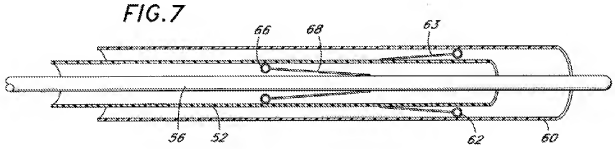
For at least these reasons, Applicant submits that Myler does not anticipate dependent claims 4-6, 8-9, 11, and 16. Applicant requests reversal of the rejection.

Dependent claim 7

Dependent claim 7 recites in part, "the at least two rings comprising a first ring and a second ring, wherein the second ring is axially spaced from said first ring, said first and second rings engaging the stent proximate a proximal end of the stent in its compact form."

As discussed above, Myler does not teach all the elements of the independent claim 1 which claim 7 depends. Furthermore, Applicant submits that Myler does not teach all the elements of dependent claim 7. As shown in Fig. 7 of Myler, when the stent is in its compact

form within the outer tube 60, only one halo, either halo 62 or halo 66, can engage the stent when the stent is in its compact form:



Although Myler states that a second halo 62 can be provided on the inner tube 52, it is spaced apart from the first halo 62 on the inner tube 52 so that "a radially inwardly directed force can be generated at a midpoint in the stent, to facilitate radial collapse" (col. 11, lines 10-19). Thus, Myler does not teach that the second ring engages the stent proximate a proximal end, as recited in claim 7.

For at least this reason, Applicant submits that Myler does not anticipate dependent claim 7. Applicant requests reversal of the rejection.

Dependent claim 15

Dependent claim 15, which depends upon claims 12-14, recites in part, "wherein each of said at least two rings has an outer diameter D_r, such that $D_r > ID_{min}$, a minimum inner diameter of portions of the stent in its compacted form … wherein said stent has portions with an inner diameter ID_{max} disposed between portions of the stent having its minimum inner diameter where $ID_{min} < D_r < ID_{max}$ and each of said at least two rings is disposed intermediate the minimum inner diameter portions."

As discussed above, Myler does not teach each and every element of independent claim 12 from which claim 15 depends. Furthermore, Applicant submits that Myler does not teach each and every element of dependent claim 15. As an example, Applicant submits that Myler does not teach "each of said at least two rings disposed intermediate the minimum inner diameter portions," as recited in claim 15.

The Final Office Action asserted that the halos 62,66 of Myler are the rings as recited in independent claim 12. The Examiner considers the projections 26 of Myler to be the inner diameter portions of the stent, since the halos 62,66 are seated in the projections 26 of the stent 10, the halos 62,66 of Myler are not "disposed intermediate the minimum inner diameter portions." (see e.g. col. 10, lines 54-55). This can be seen in Fig. 11, of Myler:

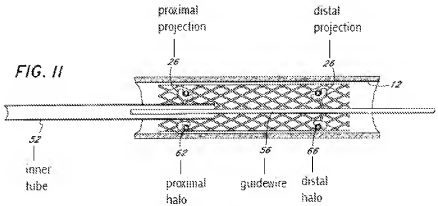


FIG. 11

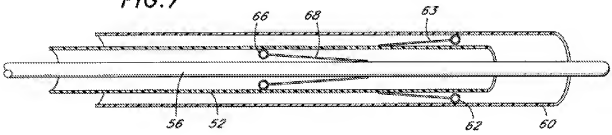
For at least these reasons, Applicant submits that Myler does not anticipate dependent claim 15. Applicant requests reversal of the rejection.

Independent claim 20

Independent claim 20 recites, in part, "with the stent in a compact form proximate a distal end of the catheter, the stent underlying the sheath and overlying at least two rings, the at least two rings assisting in the compression of the stent to the compact form from a partially deployed form."

Applicant submits that Myler does not teach or suggest all the elements of claim 20. For example, Applicant submits that Myler does not teach or suggest the stent underlying the sheath and overlying at least two rings. As shown in Fig. 7 of Myler, when the stent is in its compact form within outer sheath 60, the stent will only overlay one halo, halo 62:

FIG. 7



For at least this reason, Applicant submits that Myler does not anticipate claim 20 and requests reversal of the rejection.

Dependent claim 22

Dependent claim 22 recites, in part, "said step of selectively displacing the at least two rings relative to the sheath to urge displacement of said stent relative to the sheath to enable selective extension and retraction of the stent relative to a distal end of the sheath includes engaging the inner surface of the stent between portions of the stent having a minimum inner diameter."

Applicant submits that Myler does not teach or suggest all the elements of dependent claim 22. For example, Applicant submits that Myler does not teach "engaging the inner surface of the stent between portions of the stent having a minimum inner diameter," as recited in claim 22.

The Final Office Action asserted that the halos 62,66 of Myler are the rings as recited in independent claim 20. Applicant submits that Myler does not teach that the stent 10 has portions with a minimum inner diameter. If the projections 26 of Myler are considered to be "portions of the stent having a minimum inner diameter" as recited in claim 22, Applicant submits that since the halos 62,66 are seated in the projections 26, the halos 62,66 are not engaging the inner surface of the stent between the projections. Therefore, Myler does not teach each and every element of dependent claim 22.

For at least this reason, Applicant submits that Myler does not anticipate dependent claim 22. Applicant requests reversal of the rejection.

CONCLUSION

Instant claims 1-9, 11-17, 20 and 22 are patentably distinct over Myler. Consequently reversal of the rejection is respectfully requested.

Respectfully submitted,

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(J) Claims Appendix

1. A stent delivery system for transporting and deploying an expansible stent, said stent delivery system comprising:

A) delivery means for positioning the stent at a selected position in the patient's body, said delivery means including a sheath normally overlying the stent in its compact transport form, the stent having an inner surface, the sheath having a ring, the ring forming a distal end of the sheath, the ring assisting in the compression of the stent to the compact transport form from a partially deployed form, and an inner core normally underlying the stent in its compact transport form, and

B) deployment means for selectively deploying and retracting the stent relative to said sheath, said deployment means including at least two rings attached to and extending from said inner core and engaging the inner surface of the stent in its compact condition.

2. A stent delivery system as recited in claim 1 wherein an outer diameter of at least one of said at least two rings is greater than a minimum inner diameter (ID_{min}), of portions of the stent in its compacted form.

3. A stent delivery system as recited in claim 2 wherein at least one of said at least two rings engage the stent proximate a proximal end of the stent in its compact transport form.

4. A stent delivery system as recited in 3 wherein said delivery means further includes a handle disposed at a proximal end of said sheath and said inner core, said handle having a first actuator means for proximally retracting said sheath relative to said inner core and a second actuator means for distally displacing said inner core relative to said sheath, such that selective manipulation of said first and second actuator means enables selective deployment of the stent in an expanded form outside of said sheath and retraction of the stent within said sheath from a partially deployed state.

5. A stent delivery system as recited in claim 1 wherein said delivery means is adapted for use in a working channel of an endoscopic device of the type having a viewing channel, said delivery means including visible indicia proximate its distal end visible through the viewing channel of the endoscopic device indicating the extent of deployment of the stent.

6. A stent delivery system as recited in claim 5 wherein said delivery means further includes a handle disposed at a proximal end of said sheath and said inner core, said handle having a first actuator means for proximally retracting said sheath relative to said inner core and a second actuator means for distally displacing said inner core relative to said sheath, such that manipulation of said first and second actuator means enables selective deployment of the stent in an expanded form outside of said sheath and retraction of the stent in the compact form within said sheath.

7. A stent delivery system as recited in claim 1, the at least two rings comprising a first ring and a second ring, wherein the second ring is axially spaced from said first ring, said first and second rings engaging the stent proximate a proximal end of the stent in its compact form.

8. A stent delivery system as recited in claim 7 wherein said delivery means further includes a handle disposed at a proximal end of said sheath and said inner core, said handle having a first actuator means for proximally retracting said sheath relative to said inner core and a second actuator means for distally displacing said inner core relative to said sheath, such that manipulation of said first and second actuator means enables selective deployment of the stent in an expanded form outside of said sheath and retraction of the stent within said sheath from a partially deployed condition in the compact form.

9. A stent delivery system as recited in claim 8 wherein said delivery means is adapted for use in a working channel of an endoscopic device of the type having a viewing channel, said delivery means including visible indicia proximate its distal end visible through the viewing channel of the endoscopic device indicating the extent of deployment of the stent.

11. A stent delivery system as recited in claim 1 wherein said delivery means is adapted for use in a working channel of an endoscopic device of the type having a viewing channel, said delivery means including visible indicia proximate its distal end visible through the viewing channel of the endoscopic device indicating the extent of deployment of the stent.

12. An elongated, tubular stent delivery system for transporting a stent in a compact form within a patient's body for selective deployment of the stent in an expanded form within a patient's vessel comprising a distal end region including a sheath and a flexible core at the distal end region for overlying and underlying, respectively, a stent carried at the distal end region of the delivery system in the compact form, the stent having an inner surface, and a proximal end region including a first handle portion connected to the sheath and a second handle portion connected to the core to enable relative axial displacement of the sheath and the core, the improvement comprising at least two rings engaged to and extending from the core to engage the inner surface of the stent disposed in the compact form within said sheath such that upon the displacement of the sheath relative to the core the stent moves relative to the sheath, the sheath comprising a ring, the ring forming a distal end of the sheath, the ring assisting in the compression of the stent to the compact form from a partially deployed form.

13. A tubular stent delivery system as recited in claim 12 wherein each of said at least two rings has an outer diameter D_r, such that $D_r > ID_{min}$, a minimum inner diameter of portions of the stent in its compacted form.

14. A tubular stent delivery system as recited in claim 13 wherein at least one of said at least two rings engages the stent proximate a proximal end of the stent in its compact form.

15. A tubular stent delivery system as recited in claim 14 wherein said stent has portions with an inner diameter ID_{max} disposed between portions of the stent having its minimum inner diameter where $ID_{min} < D_r < ID_{max}$ and each of said at least two rings is disposed intermediate the

minimum inner diameter portions.

16. A tubular stent delivery system as recited in claim 15 wherein said delivery system is adapted for use in a working channel of an endoscopic device of the type having a viewing channel and the distal end of the stent having indicia proximate the distal end of the core, said indicia being of the type visible through the viewing channel of an endoscopic device and indicating the extent of deployment of the stent.

17. A tubular stent delivery system as recited in claim 12, the at least two rings comprising a first ring and a second ring, wherein the second ring is secured to the core proximate to and axially spaced from the first ring, wherein said first and second rings are proximally spaced from a distal end of the stent in its compacted delivery state.

20. A method for delivering and selectively deploying a stent comprising the steps of:

A) inserting an axially extending catheter within the body of a patient, the catheter having an exterior sheath, the exterior sheath having a ring, the ring forming a distal end of the exterior sheath, with a stent in a compact form proximate a distal end of the catheter, the stent underlying the sheath and overlying at least two rings, the at least two rings assisting in the compression of the stent to the compact form from a partially deployed form,

B) urging the distal end of the catheter through the patients body to position the distal end at a selected location, and

C) selectively displacing the at least two rings relative to the sheath to urge the displacement of said stent relative to the sheath to enable selective extension and retraction of the stent relative to a distal end of the sheath.

22. A method for delivering and selectively deploying a stent as recited in claim 20 wherein the stent is self-expansive and said step of selectively displacing the at least two rings relative to the sheath to urge displacement of said stent relative to the sheath to enable selective extension and retraction of the stent relative to a distal end of the sheath includes engaging the inner surface of

the stent between portions of the stent having a minimum inner diameter.

(K) Evidence Appendix - None

(L) Related Proceedings Appendix - None